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10/759,797

01/17/2004

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01/04/2007

EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                 |                   |  |
|------------------------------|-----------------|-------------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)      |  |
|                              | 10/759,797      | SHADDUCK, JOHN H. |  |
|                              | Examiner        | Art Unit          |  |
|                              | Phil Wiest      | 3761              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I: Claims 1-10 in the reply filed on 11/3/06 is acknowledged.
2. Claims 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/3/06.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: "subconjunctival" is spelled incorrectly on line 2 of the claim. Appropriate correction is required.
4. Claim 5 objected to because of the following informalities: Claim 5 does not exist. Claims should be renumbered accordingly. Appropriate correction is required.
5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 6-10 have been renumbered 5-9.

### ***Claim Rejections - 35 USC § 112***

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the stent is implanted at 6 o'clock or 12 o'clock with respect to the subconjunctival plane or the limbus. Additionally, the specification does not mention the angle of insertion relative to the limbus or subconjunctival plane. The only mention of "6 o'clock" or "12 o'clock" is on page 4 of the specification, and refers to the location of the lymphatic vessels.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 5-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al. (US 5,968,058).
10. With respect to Claims 1 and 2, Richter et al. disclose a method for treating ocular hypertension in a human eye comprising implanting a stent 30 having an interior flow passageway 38 between a region of the subconjunctival plane 18 and the uveoscleral plane (12, 14) (Column 1, Lines 38-48). See Figure 1. Regarding

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placement of the stent proximate the lymphatic vessel network, Figure 1 further discloses that the stent 30 is inserted in the same vicinity as claimed by applicant.

Richter et al. further disclose that the stent 30 extends radially inward from the subconjunctival plane 18 to the uveoscleral plane (12, 14), as per Claim 2.

11. With respect to Claims 4 and 5, Richter et al. disclose that the stent 30 is provided with a spur portion 52 that contacts the sclera. Said spur portion 52 is "...made of a shape memory material such as PMMA or nitinol, such that the spur 52 is flat against the tube when cool but expands to its final shape when subjected to the heat of the eyeball 10" (Column 6, Lines 4-14). Richter et al. further disclose that the entire implant 30 can be made of a shape memory material from a group including at least PMMA and nitinol (Column 8, Line 64 – Column 9, Line 3). The stent 30 is therefore capable of moving to a memory shape in either the uveoscleral plane or the subconjunctival plane.

12. With respect to Claim 6, Richter et al. disclose a method of controlling intraocular pressure (IOP) comprising implanting a stent 30 having an interior flow channel 38 therein between the interior of the eye (anterior chamber 20) and the subconjunctival plane 18. Regarding placement of the stent proximate the lymphatic vessel network, Figure 1 further discloses that the stent 30 is inserted in the same vicinity as claimed by applicant. Regarding the lymphatic system naturally controlling outflows and IOP, it is inherent that, once the shunt is in place, fluid will flow from the higher pressure area to the lower pressure area (Bernoulli's principle).

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13. With respect to Claim 7, Richter et al. disclose that the stent 30 comprises a fenestrated outflow end 50. Outflow end 50 comprises a plurality of U-shaped passageways 156 that enable the outflow of aqueous humor from the axial outlet 151 into the reservoir 154. Richter et al. further disclose that the stent 30 comprises an elliptical base 144 and an outer rim 146 that extend generally circumferentially in the subconjunctival plane 18 (the outflow end 50). See Figure 12 and Column 8, Lines 10-18.

14. With respect to Claim 9, Richter et al. disclose that the method of Claim 6 further comprises implanting a fenestrated inflow end 40 within the anterior chamber (Column 8, Lines 45-48). The inflow end 40 comprises a plurality of circumferential holes that connect the tube passage 38 and the anterior chamber 20. See Figure 3.

***Claim Rejections - 35 USC § 103***

15. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al. in view of Cabib et al. (US 6,556,853). Richter et al. disclose a method of controlling IOP comprising implanting a stent 30 having an interior flow channel 38 therein between the interior of the eye (anterior chamber 20) and the subconjunctival plane 18, as per Claim 6. Richter et al., however, do not disclose that the method of Claim 6 further comprises the step of identifying the lymphatic network by dye injection prior to the implanting step. Cabib et al. discloses a method of imaging the eye wherein it is disclosed that the step of intravenously injecting a dye for the determination of ocular vasculature and blood flow is well established in the art (Column 7, Lines 18-34).

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It would have been obvious to one skilled in the art at the time of invention to combine the method of controlling IOP of Richter et al. with the dye injection of Cabib et al. in order to easily locate the lymphatic network prior to surgically implanting the stent 30 proximate the lymphatic network.

### ***Conclusion***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRW  
12/21/06

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.